

13
Conclude

appearing in a patient suffering from anti-phospholipid syndrome which comprises administering to said patient an effective amount of a multichain peptide-oligomer/polymer conjugate or a multiple antigen peptide according to claim 2(v).

REMARKS

Claims 1-21 presently appear in this case. No claims have yet been acted upon on the merits. All of the claims have been subject to restriction and election requirements. These requirements are respectfully traversed.

The examiner has imposed a complex and confusing restriction requirement, designating five sub-genera and twenty allegedly patentably distinct groups. This restriction requirement is respectfully traversed.

The examiner acknowledges the "371" status of the present application and that, in view of the status, unity of invention exists when there is a technical relationship among the claimed inventions involving one or more special technical features, i.e., those technical features that define a contribution which each of the inventions considered as a whole makes over the prior art. Here, the examiner states "it may be true that the specific tetrapeptides recited in claim 2 are novel". In any event, the examiner has not cited any reference to show that these tetrapeptides are not novel. If the tetrapeptides are novel, then certainly the cyclic derivatives thereof, those which have been replaced by a D-

isomer, chemical derivatives thereof and multichain peptide-oligomer/polymer conjugates which include these sequences share the same technical feature and should all be examined in the same case, particularly in view of the existence of a true generic claim 1. Thus, unless and until the examiner shows that the sub-genera of G5 is unpatentable over the prior art, then all of claim 2 should be examined in this case as all of the species included therein share the same special technical feature.

In order to be responsive, applicant hereby elects Group IV, including claims 1-5, 7-12, 16 and 17, which includes sub-genera G3 and G5. Note that as both G3 and G5 are intended to be included in Group IV, the examiner should have included claims 3-5 with the specified claims falling within this group. It should be noted, however, that the multichain peptide-oligomer/polymer conjugate and the multiple antigen peptide really should belong to a single sub-genus as the concept for former definitions (v) and (vi) of claim 2 is the same; namely, to present molecules having more than one peptide of the invention associated with the multifunctional oligomeric/polymeric backbone or a multifunctional small molecule, e.g., diaminoalkanoic acid, in order to obtain an improved therapeutic activity. Therefore, the combination of both definitions is proper and should obviate the need for restriction between Groups IV and V. In order to clarify this, claim 2 has been amended to insert a new sub-paragraph (v) drawn to all of the possible conjugates. Thus, at the

very least, it is requested that Groups IV and V be examined together.

With respect to claims 16-20, the examiner explains the reason for restriction, referring to MPEP §806.05(c). However, this section of the MPEP is not applicable to unity of invention rejections for §371 applications. Nevertheless, it is noted that the examiner has indicated that if the elected group is found allowable, that novelty would likely accrue to claims that are drawn to a kit.

The same is true with respect to claims 6-15. The examiner states that MPEP §806.05(h) is applicable, but this is not the case for §371 applications. Nevertheless, the examiner has indicated that if the elected group is found allowable, then the corresponding method-of-use claims will be rejoined for further examination. The examiner also states that further rejoining of non-elected embodiments would be likely in the event that Group II were elected and claims therein found allowable. However, "chemical derivatives" are not patentably distinct from the derivatized peptides as chemical derivatives do not change one amino acid to another. Accordingly, it is urged that the examiner that chemical derivatives be examined with the elected species.

The examiner has also required applicant to elect a single disclosed species for prosecution on the merits. In order to be responsive, applicant hereby elects the species of SEQ ID NO:3. Claims 1-3 read on the elected species.

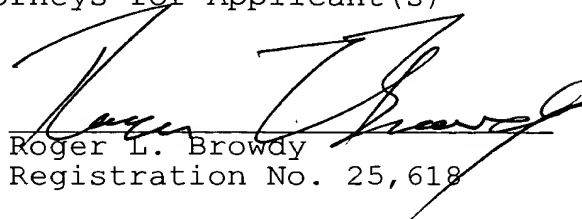
Accordingly, reconsideration and withdrawal of the restriction requirement and examination on the merits of all the claims now present in the case is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made".

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By


Roger L. Browdy
Registration No. 25,618

RLB:rd
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\bN\y\yEDA\blank3\pTO\AmendmentC.doc

Version with Markings to Show Changes Made

In the Claims

Claim 2, 5 and 19 have been amended as follows:

2 (~~Amended~~Twice-amended). The peptide or derivative according to claim 1, being selected from the group consisting of:

(i) a peptide of at least 4 amino acid residues comprising a sequence selected from:

(a) Thr Pro Arg Val (residues 1-4 of SEQ ID NO:1)

(b) Lys Ala Thr Phe (residues 3-6 of SEQ ID NO:4)

(c) Leu Arg Val Tyr (residues 4-7 of SEQ ID NO:7)

(ii) a cyclic derivative of a peptide of (i);

(iii) a peptide according to (i) or (ii) in which one or more amino acid residues have been replaced by the corresponding D-isomer or by a non-natural amino acid residue;

(iv) a chemical derivative of a peptide according to (i) - (iii); and

(v) a conjugate selected from the group consisting of: (a) a conjugate comprising two or more of the same or different peptides or peptide derivatives of (i) to (iv) attached to a native or synthetic oligomeric or polymeric backbone; and (b) a conjugate comprising two to eight of the same or different peptides or peptide derivatives of (i) to (iv) anchored onto a diaminoalkanoic acid core. ~~a multichain~~

~~peptide-oligomer/polymer conjugate comprising two or more of the same or different peptides or peptide derivatives (i) to (iv) attached to a native or synthetic multifunctional oligomeric or polymeric backbone; and~~
~~———— (vi) a multiple antigen peptide in which two to eight same or different peptides or peptide derivatives (i) to (iv) are anchored onto a diaminoalkanoic acid core.~~

5 (~~Amended~~Twice-amended). The peptide according to claim 2 (i)(c) of a sequence selected from:

Thr Leu Arg Val Tyr Lys (residues 3-8 of SEQ ID NO:7)

Thr Lys Leu Arg Val Tyr (SEQ ID NO:5)

Thr Leu Leu Arg Val Tyr (SEQ ID NO:6)

Cys Ala Thr Leu Arg Val Tyr Lys Gly Gly (SEQ ID NO:7).

19 (~~Amended~~Twice-amended). A method for inactivating B cells responsible for the production of autoantibodies appearing in a patient suffering from anti-phospholipid syndrome which comprises administering to said patient an effective amount of a multichain peptide-oligomer/polymer conjugate or a multiple antigen peptide according to claim ~~12~~12(v).